

**REMARKS**

**Preliminary Remarks**

This response is being timely filed as it is being filed within the three-month shortened statutory period set forth in the March 17, 2003 official action. On June 3, 2003, the undersigned conducted a personal interview with Examiner Edward Webman, in which two of the inventors, Dr. Anatoly Dritschilo and Dr. Manny Subramanian, participated. Also present was Mr. Ray Woods, an in-house patent agent for the licensee of this patent application. The applicants thank Examiner Webman for his time and consideration during the interview. The content of the personal interview will be summarized in detail below.

After entry of this amendment, claims 1-16 and 34-70 will be pending in this patent application, with claims 1-16 having been withdrawn from consideration after the applicants' response to a January 8, 2001 official action setting forth a restriction requirement. Thus, there will be an effective total of 53 pending claims, with 3 independent claims and 50 dependent claims. The applicants previously paid for a total of 33 claims, including 3 independent claims. Therefore, extra claim fees for 20 total extra claims are authorized to be charged on the attached cover sheet.

New independent claim 34 recites some of the features that were recited in cancelled independent claim 17 and improves on the clarity and readability of that claim. However, the applicants note that certain features previously recited in claim 17 are not recited in claim 34. For example, claim 34 does not recite the particular dimensions of the device, nor does it recite the particular material of which the recited device is made. Those features are now recited in the claims that depend from independent claim 34.

2 The applicants have added the feature that the device recited in claim 34 is "rigid." Support for this feature is found, *inter alia*, at page 8, lines 15-20 and page 9, lines 1-13 of the specification. Of the dependent claims, claims 45 and 64 recite a "degradable coating," support for which can be found, *inter alia*, at page 13, lines 16-21 and page 14, lines 1-2 of the specification.

New independent claim 51 recites a drug delivery system that includes "a storage cartridge." Support for the recited storage cartridge can be found, *inter alia* at page 12, lines 17-19, and in Figure 2 of the drawings.

The applicants respectfully submit that no new matter has been added. Moreover, the applicants note that a proposed claim set very similar to that presented for entry above was discussed with the examiner during the personal interview. Claims 34-70 include some linguistic refinements that were agreed upon during the personal interview.

In addition to the claim amendments, the applicants have sought authorization to amend the drawings so as to remove certain dimension lines and dimensions shown therein. The applicants have also amended the specification to include the dimensions previously shown in the drawings and to use the trademarked term GENESEED more properly.

For the examiner's convenience, the applicants note with respect to the January 8, 2001 restriction/election of species requirement that claims 36-37 and 56-57 read on the elected "metal" species of material, whereas claims 38 and 58 read on the non-elected "plastic" species of material. The remainder of the claims are generic to all species of material. Furthermore, independent claims 34 and 51 both recite the elected "nucleic acid" therapeutic agent species.

Patentability Remarks

35 U.S.C. § 102(b)

Claims 17-19, 21-22 and 29-31 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hanson *et al.*, U.S. Patent No. 5,523,092 (hereinafter the '092 patent). It is the examiner's position that the '092 patent discloses a device for delivery of a substance that is made of titanium, has particular dimensions, and includes holes. The examiner also alleges that the '092 patent discloses DNA and antibodies comprising a cytotoxin as therapeutic agents.

The applicants respectfully traverse and submit that this rejection of claims 17-19, 21-22, and 29-31 is now moot in view of the cancellation of those claims. Furthermore, the applicants respectfully submit that the rejection should not be extended to new claims 34-70.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The applicants submit that the '092 patent does not disclose each and every element of independent claims 34 and 51, or the claims that depend from them.

Independent claims 34 and 51 each recite a “substantially hollow, rigid container.” During the personal interview, Drs. Dritschilo and Subramanian showed Examiner Webman a number of prototype devices embodying that feature and other features of claims 34-70. As the applicants explained during the personal interview, the ‘092 patent does not disclose at least that feature of claims 34 and 51.

The applicants submit that the ‘092 patent discloses a flexible catheter with a spiral shaped substance delivery end segment that deformably changes shape to remain in position during operation. This is shown in figures 4 and 5 of the ‘092 patent and is explained, *inter alia*, at column 9, lines 24-33, which state that:

the substance delivery segment 122 is moveable among at least three positions: a first or resting position wherein it has a first shape (similar to the embodiment shown in FIG. 1); a second position wherein it has a second shape (as shown in FIG. 2); and a third or operative position operative position [sic] wherein it has a third shape...(similar to the embodiment shown in FIGS. 4-5).

Therefore, the device disclosed in the ‘092 patent is clearly not rigid.

Moreover, the applicants submit that the examiner’s position on the ‘092 reference is incorrect in several respects. First, the applicants disagree with the examiner’s assertion that the ‘092 reference discloses the use of titanium as a suitable material for its catheter. The examiner points to column 11, line 46 in support of this assertion, but the applicants submit that the examiner takes the mention of titanium in that passage out of context. The passage at column 11, line 46 of the ‘092 reference actually states that:

In a presently preferred embodiment, the substance delivery segment 22 (see FIGS. 1-5) is constructed from nitinol (nickel/titanium alloy) such that the nitinol in the substance delivery segment 22 is normally in the first position (i.e., the rest or memory position) as shown in FIG. 1 when the device is at room temperature, e.g., about 23°-25°C. The substance delivery segment 22 can be made to assume the second position (wherein the second shape of the substance delivery segment 22 is substantially linear) by exposing the nitinol to a fluid having a temperature of between about 40°-65°C but preferably about 55°C.

The applicants note that nitinol is not titanium. Rather, nitinol is a shape memory alloy containing some titanium. Operationally, a shape memory alloy can be deformed at low temperature, but will return to an original or “memory” position if heated, hence the disclosure in the ‘092 patent of the particular temperatures that cause the alloy to assume a

second position. The applicants submit that the disclosure in the '092 patent of the shape memory alloy nitinol supports the applicants' position that the device disclosed in the '092 patent is not rigid.

Additionally, the examiner asserts that "hole diameter and wall thickness are illustrated (figure 3)" in the '092 patent. In response, the applicants submit that the hole diameters and wall thicknesses illustrated in figure 3 of the '092 patent do not anticipate the dimensional ranges that are recited in the dependent claims and cannot properly be used to reject the claims, because neither the specification nor the drawing figures of the '092 patent sets forth specific dimensions or dimensional ranges for the structures illustrated in the figures. The applicants direct the examiner's attention to MPEP § 2125, which cites *Hockerson-Halberstadt Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d, 1487, 1491 (Fed. Cir. 2000) in stating that "when the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing figures are of little value."

In view of the foregoing, the '092 patent, as a matter of law, cannot properly anticipate claims 34-70. Therefore, the applicants respectfully request that the rejection based upon 35 U.S.C. §102(b) be withdrawn and not be extended to new claims 34-70.

35 U.S.C. § 103(a)

Claims 32 and 33 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the '092 patent in view of Hebert et al., U.S. Patent No. 5,356,775 (hereinafter the '775 patent). It is the examiner's position that the '775 patent teaches that radionuclides are cytotoxins, and that it would have been obvious to use a radionuclide as disclosed in the '775 patent in the device disclosed in the '092 patent.

The applicants respectfully traverse and submit that this rejection of claims 32 and 33 is now moot in view of the cancellation of those claims. Furthermore, the applicants respectfully submit that the rejection should not be extended to new claims 34-70.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the

claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The applicants submit that the cited documents, either alone or in combination fail to teach or suggest the applicants' claimed invention, *i.e.*, fail to teach or suggest all of the claim limitations. In particular, the applicants respectfully submit that, for the reasons explained above with respect to the rejection under §102(b), the '092 patent does not disclose or suggest each and every feature recited in independent claims 34 and 51. The applicants also submit that the '775 patent does not remedy the "deficiencies" of the '092 patent, regardless of what it may disclose with respect to radionuclides.

In view of the foregoing, the applicants submit that the '775 patent, either alone or in combination with the '092 patent, cannot, as a matter of law, render the present invention obvious. Therefore, the applicants request that the rejection of the claims under 35 U.S.C. §103(a) over the '092 patent in view of the '775 patent be withdrawn and not be extended to new claims 34-70.

### III. CONCLUSION

In view of the foregoing, the applicants submit that this application is in condition for allowance. A timely notice to that effect is respectfully requested. If questions relating to patentability remain, the examiner is strongly urged to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

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Enclosure:  
Drawing Change Authorization Request

# Figure 1: Various Designs of GeneSeeds

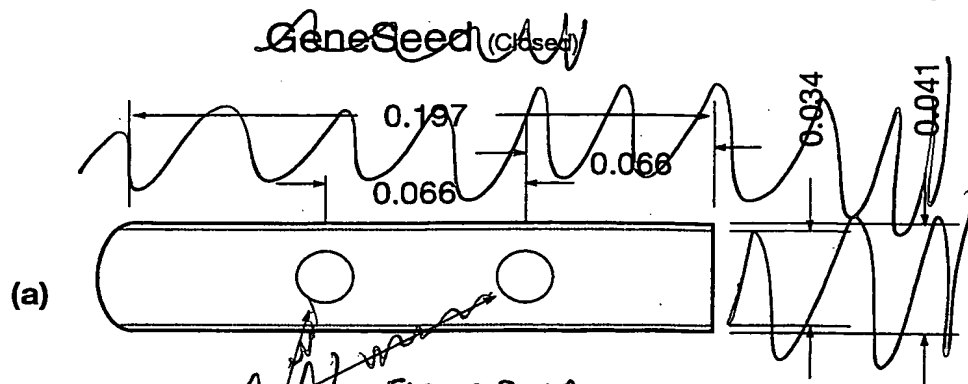


FIGURE 1A

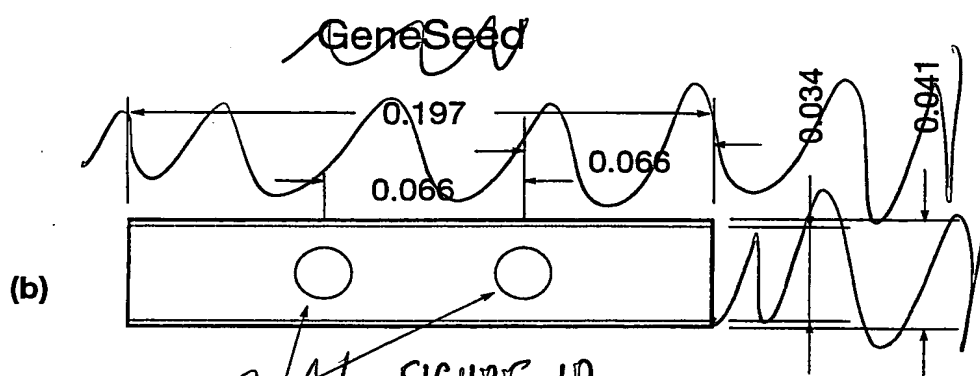


FIGURE 1B

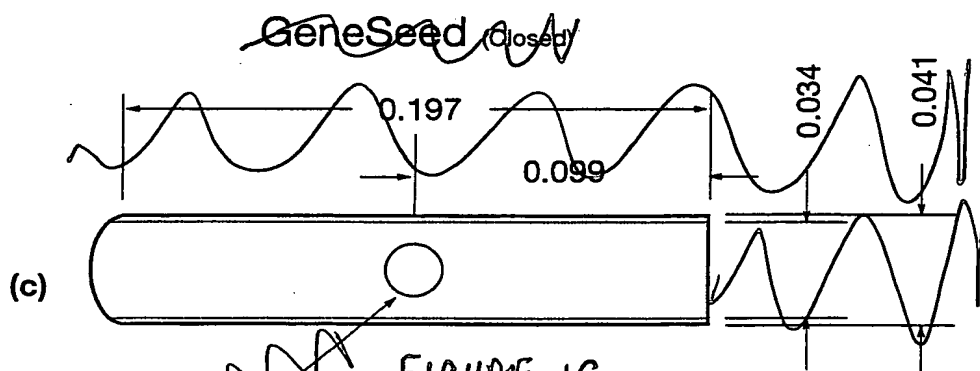


FIGURE 1C

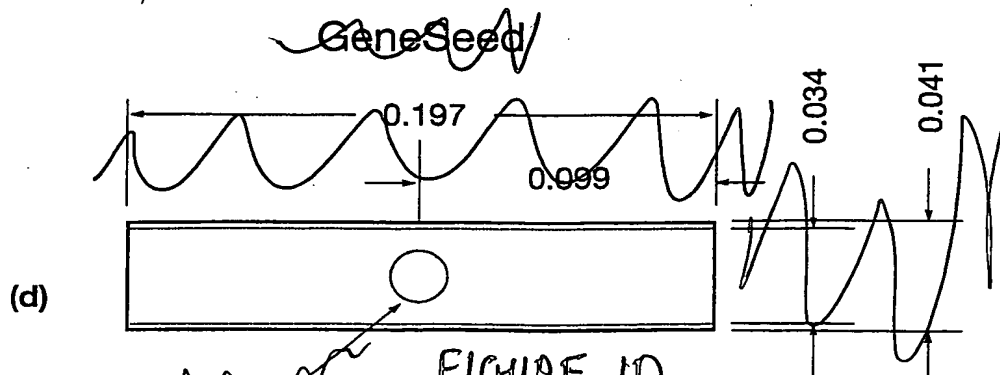
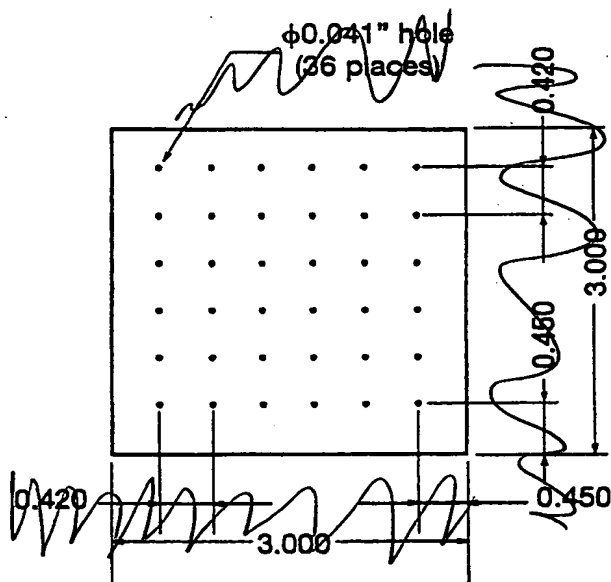


FIGURE 1D

(All dimensions are in inches.)



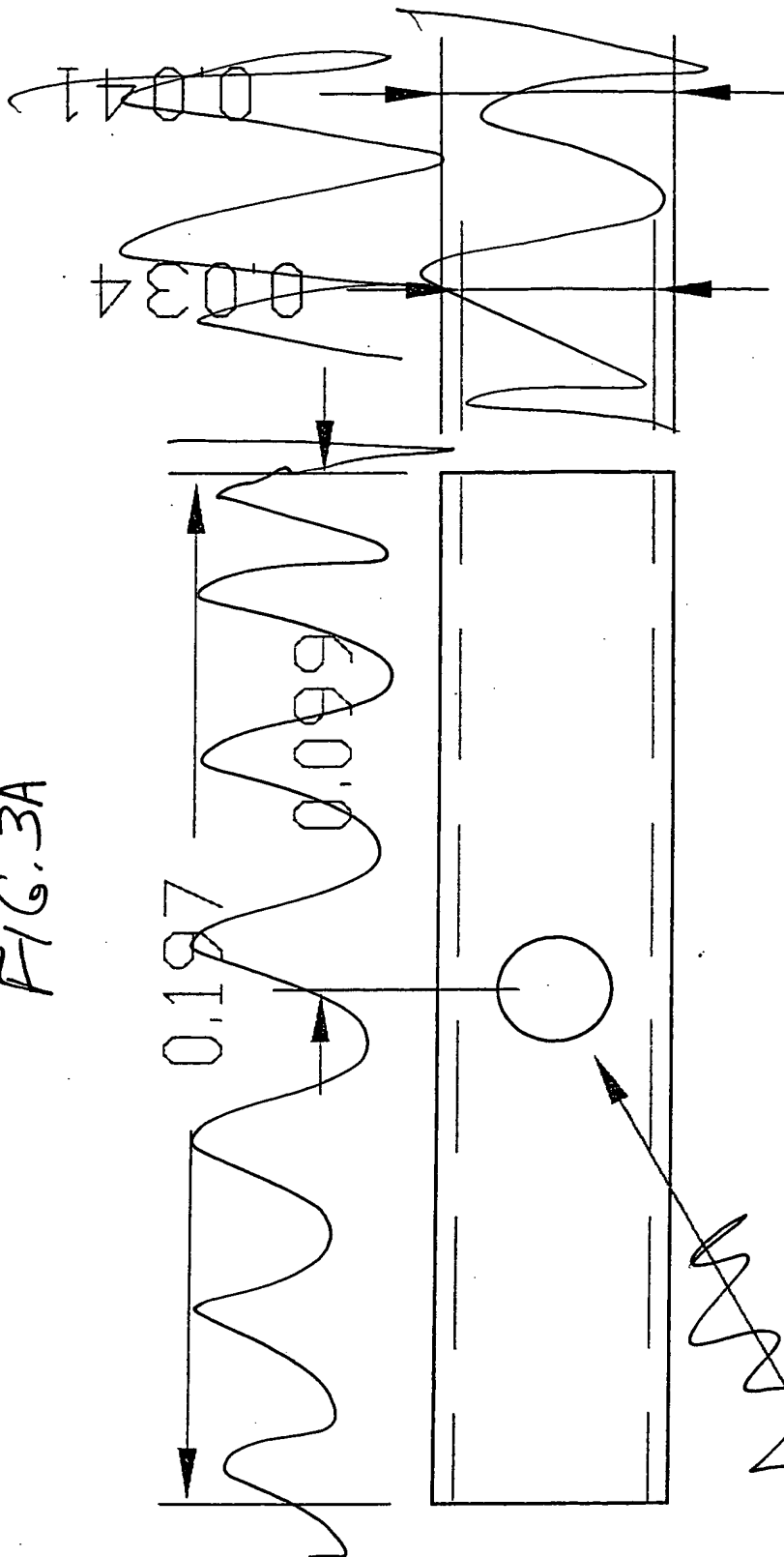
**Figure 2: ~~GeneSeed Transfer Device~~**



(All dimensions are in inches. Material: 1/8" Aluminum)



FIG. 3A



$\lambda = 0.020$

FIG 3B

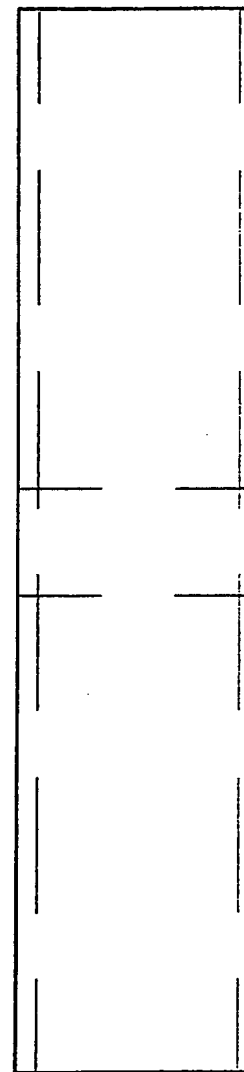
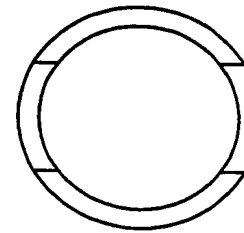


FIG 3C



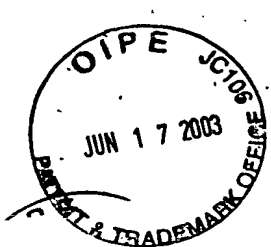


FIG. 4A

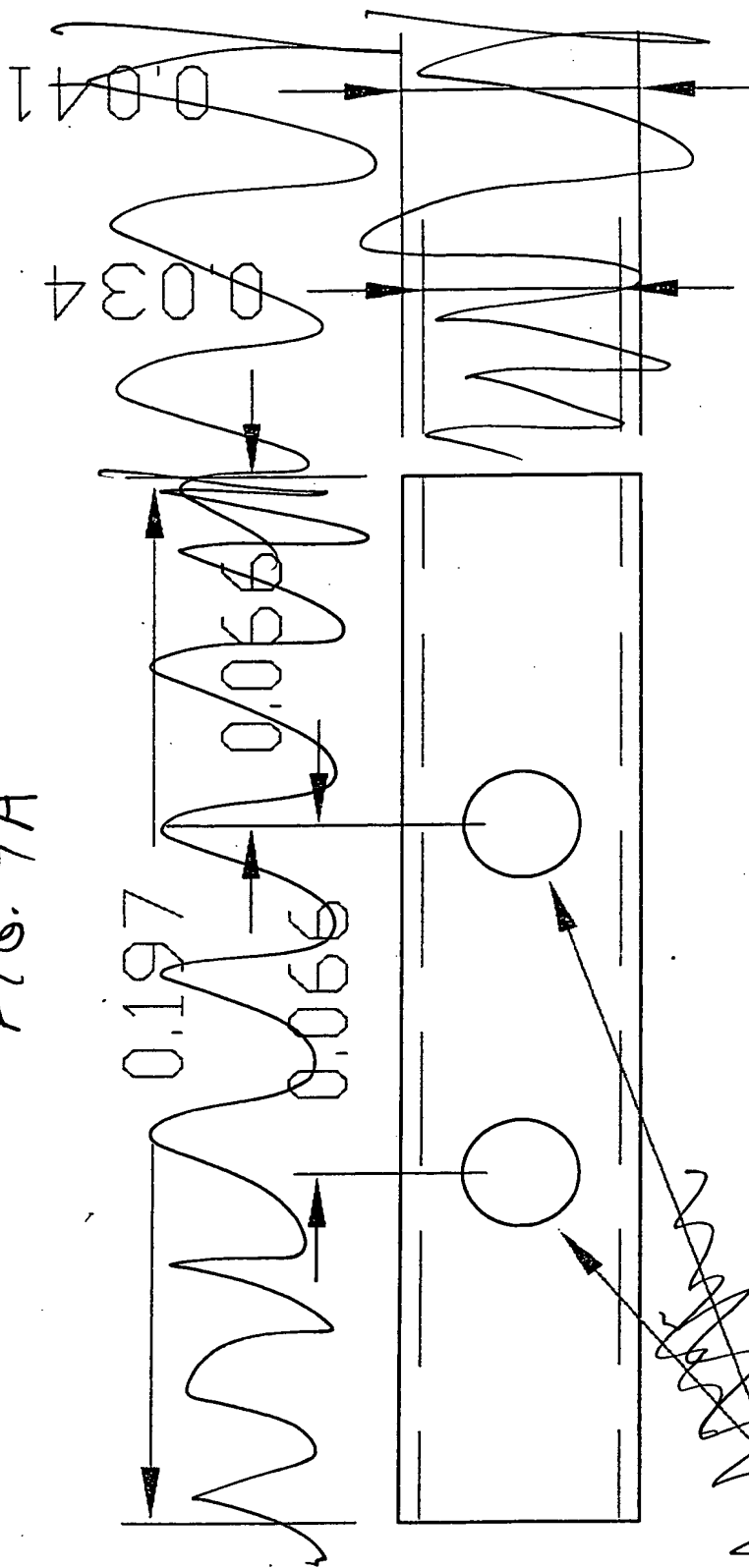


FIG 4B

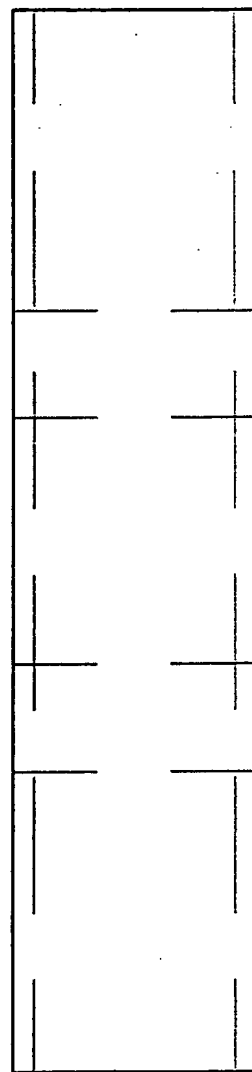


FIG 4C

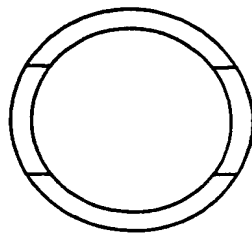


FIG. 5A

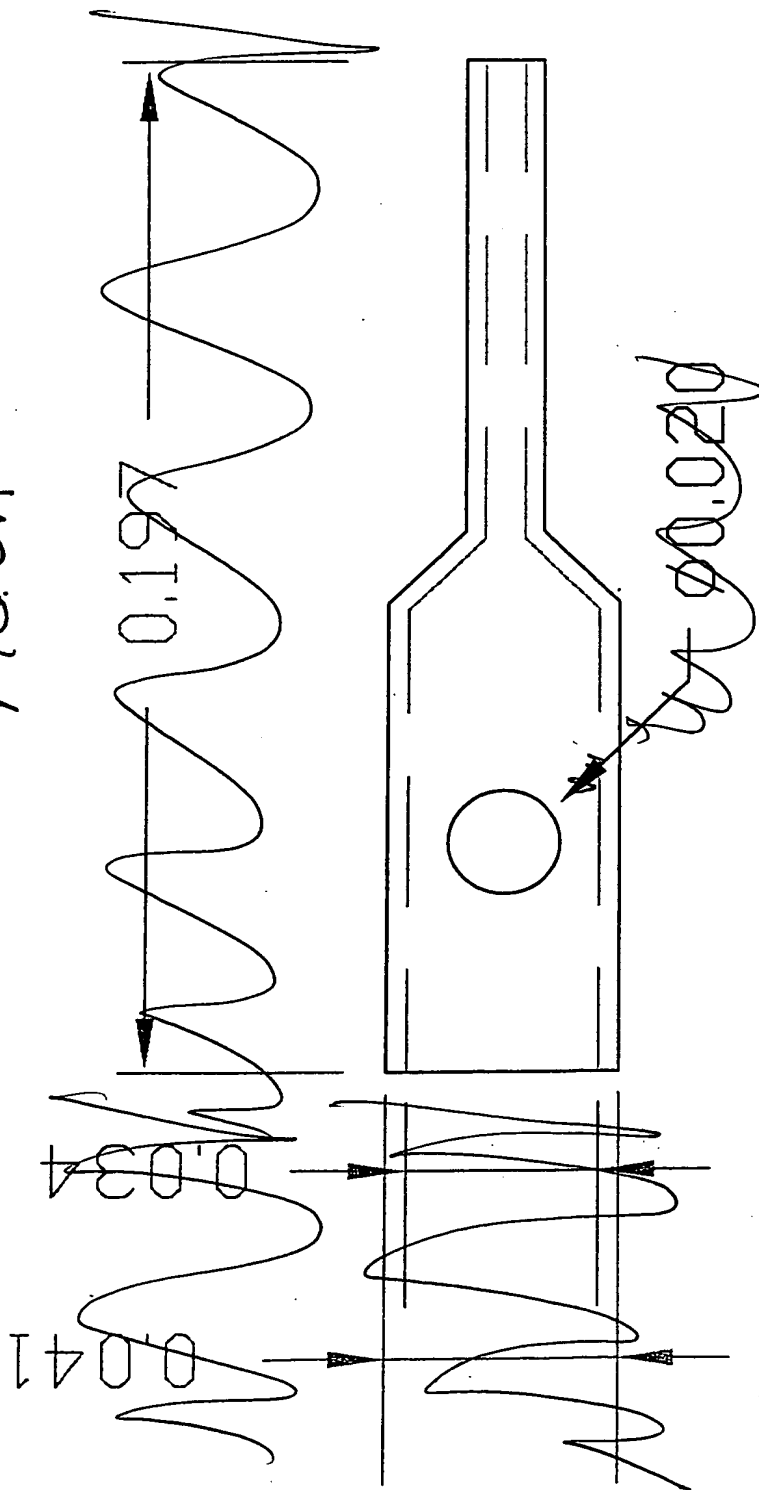


FIG 5B

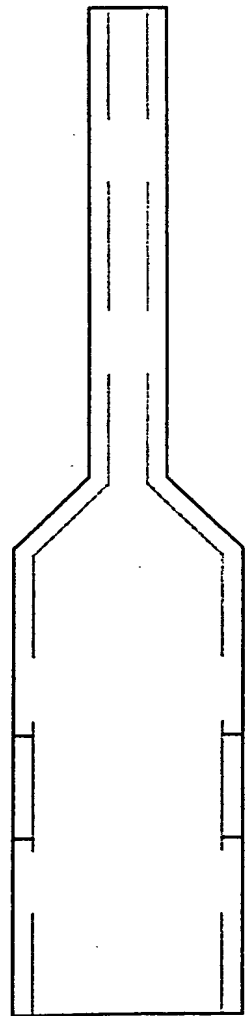
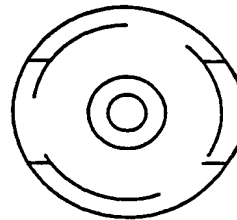


FIG 5C



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Fig. 6A

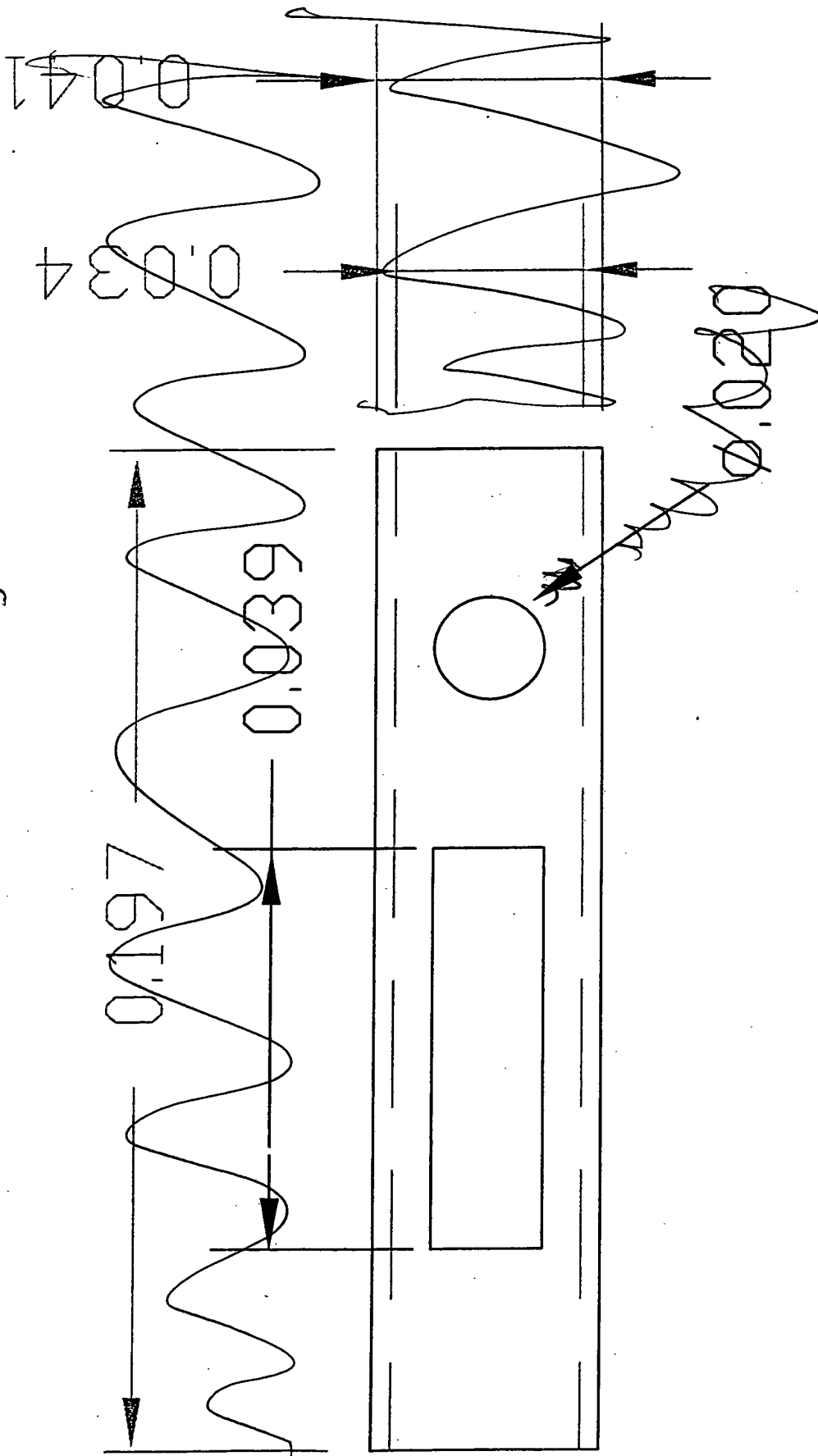


FIG 6B

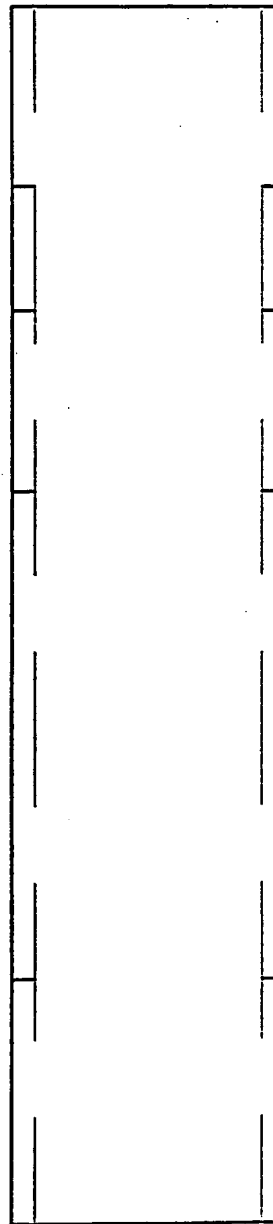


FIG-6C

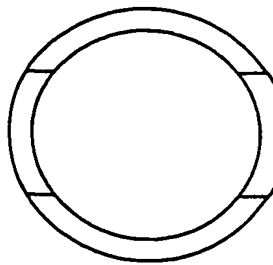




FIG. 7A

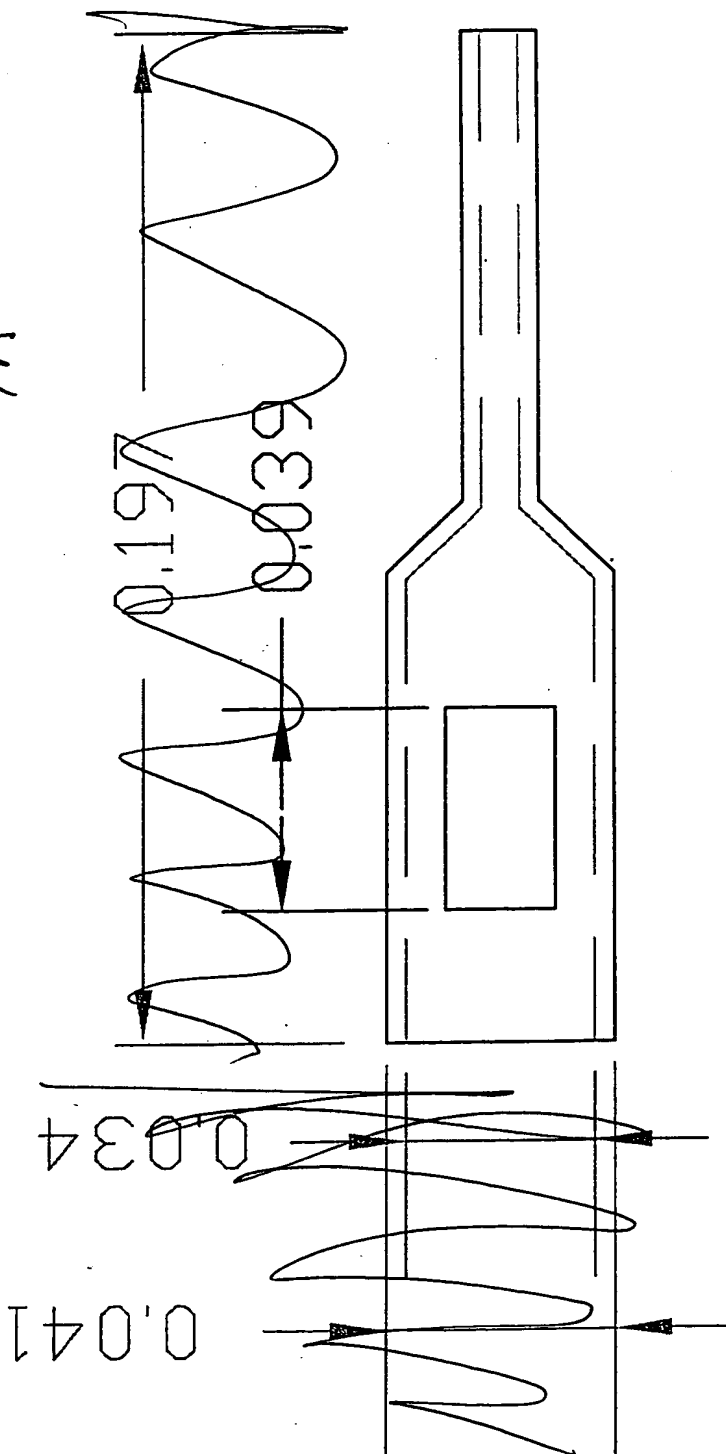


FIG 7B

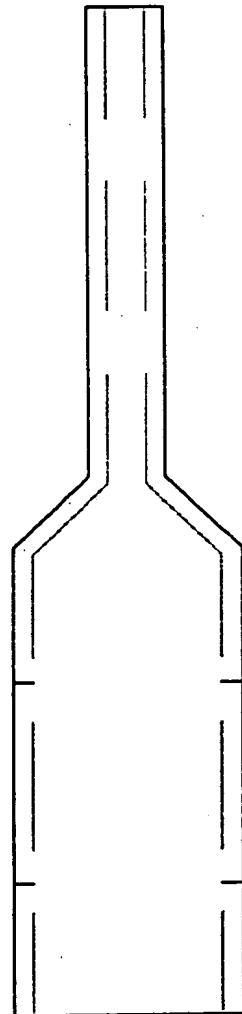
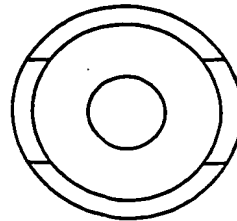
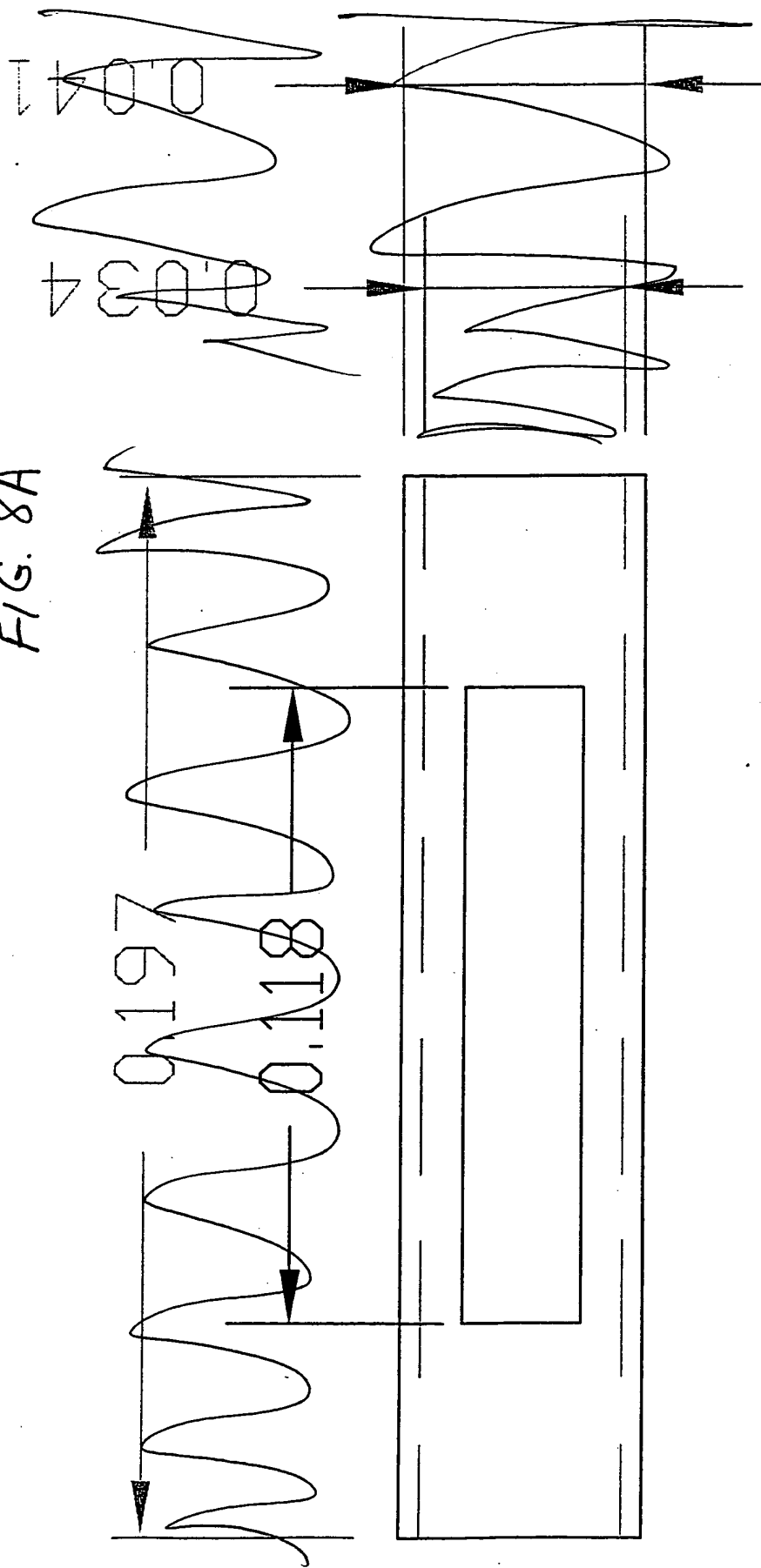


FIG 7C





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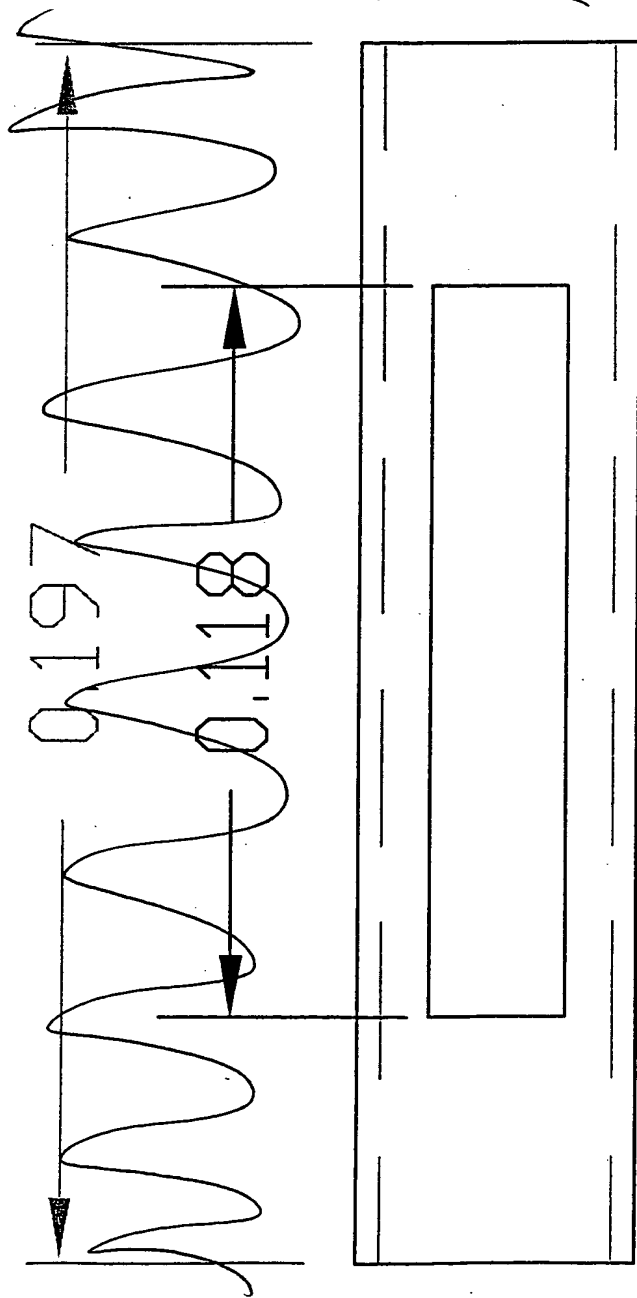


FIG 8B

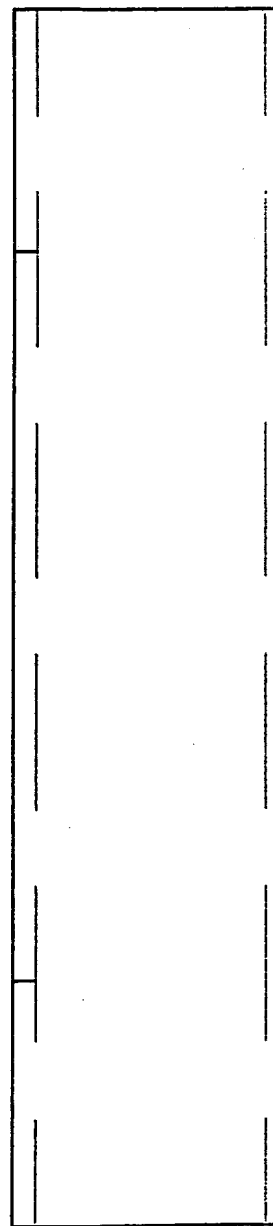


FIG-8C

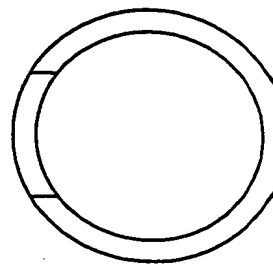


FIG. 9A

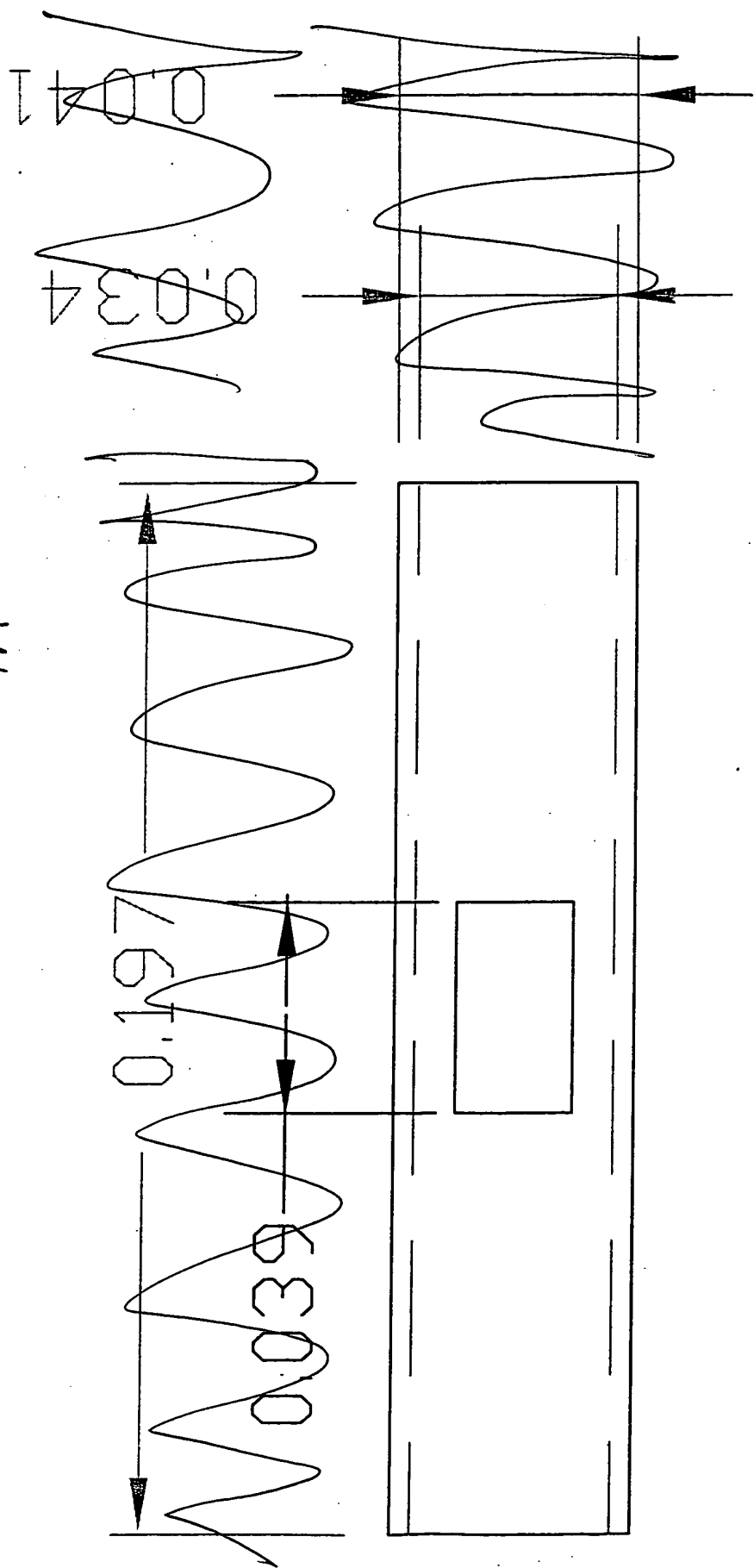


FIG. 9B

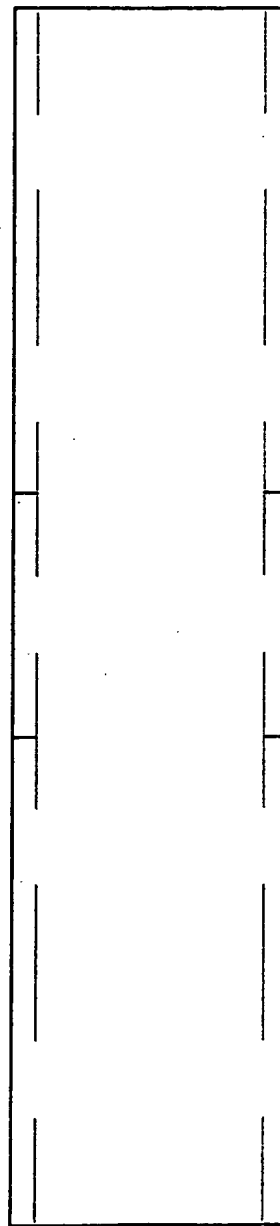


FIG. 9C

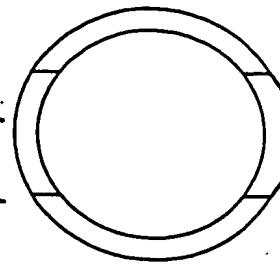


FIG. 10A

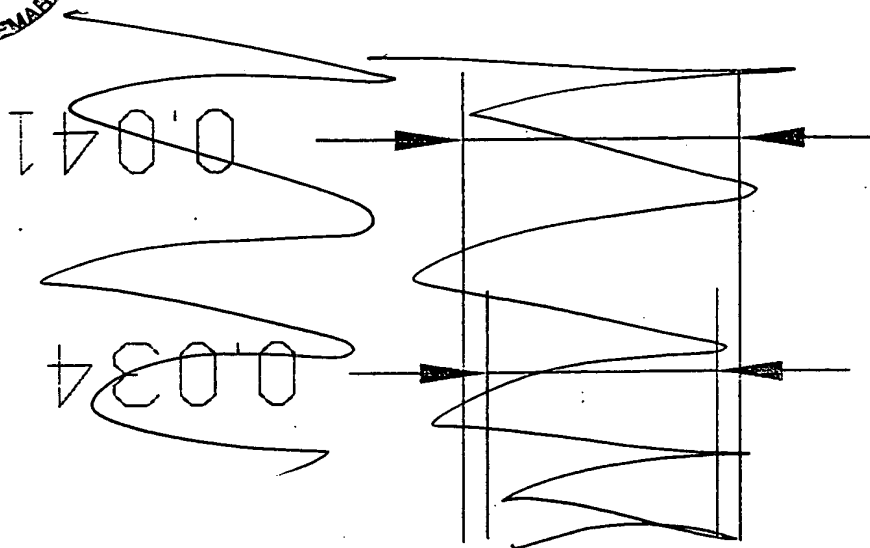
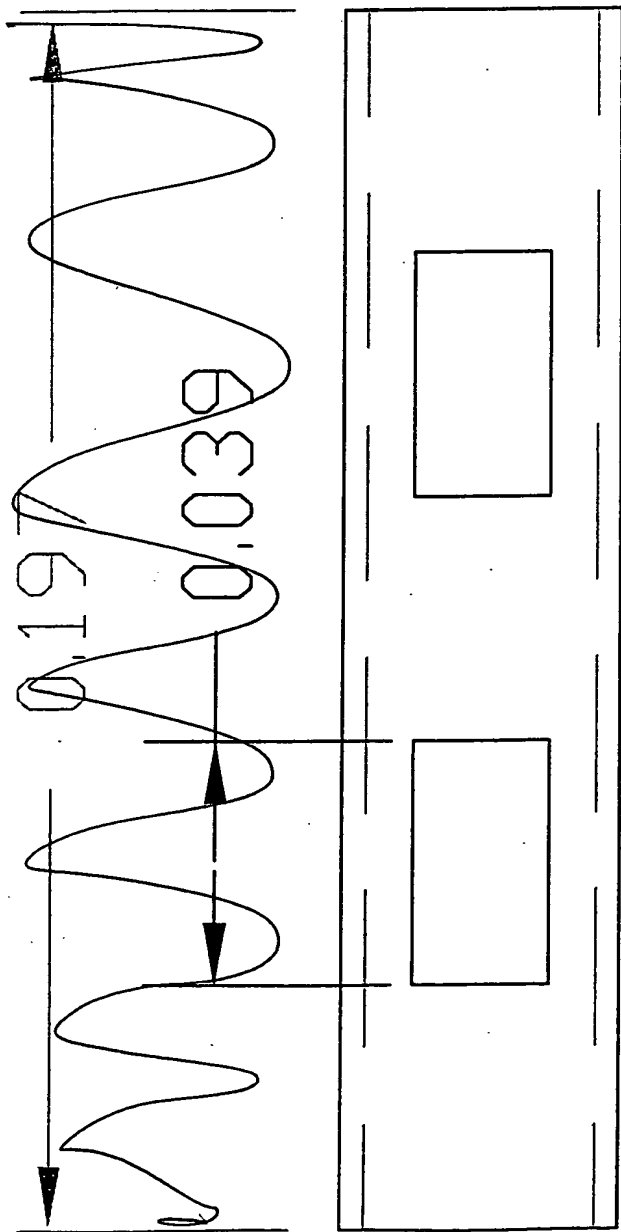


FIG 10B

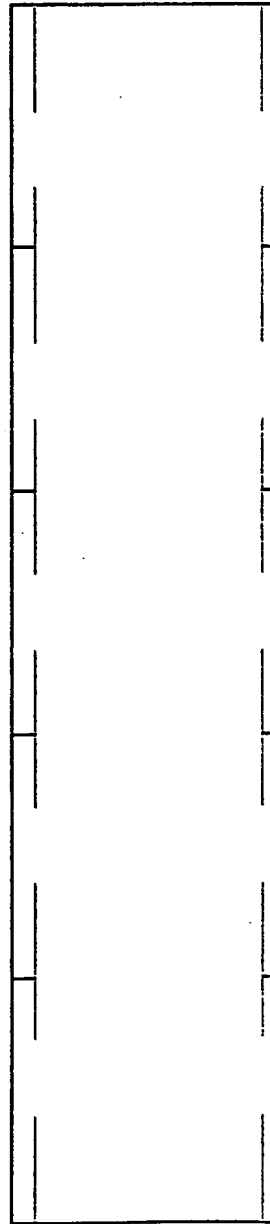


FIG-10C

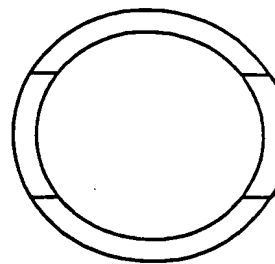






FIG 11A

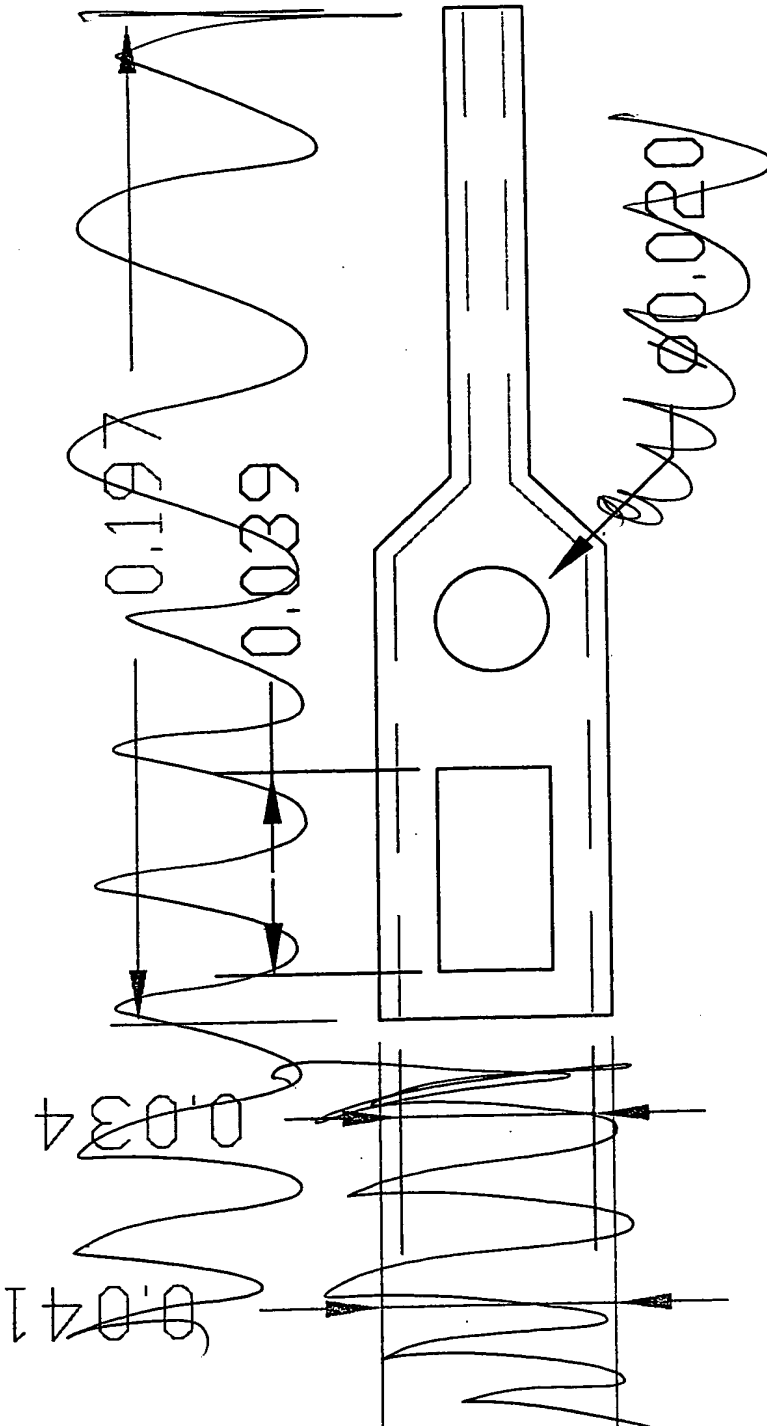


FIG 11B

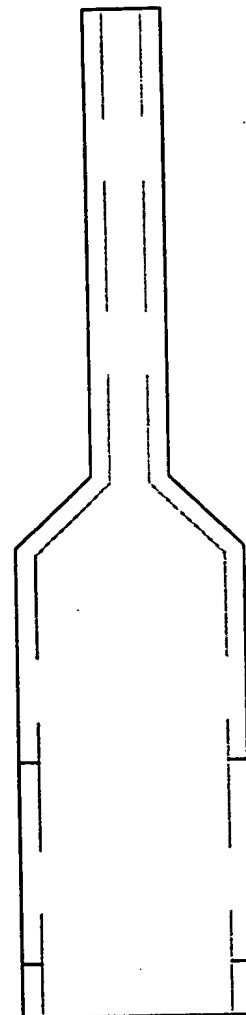


FIG 11C

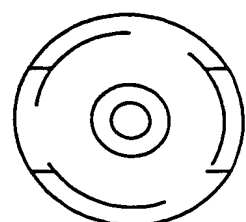


FIG. 12A

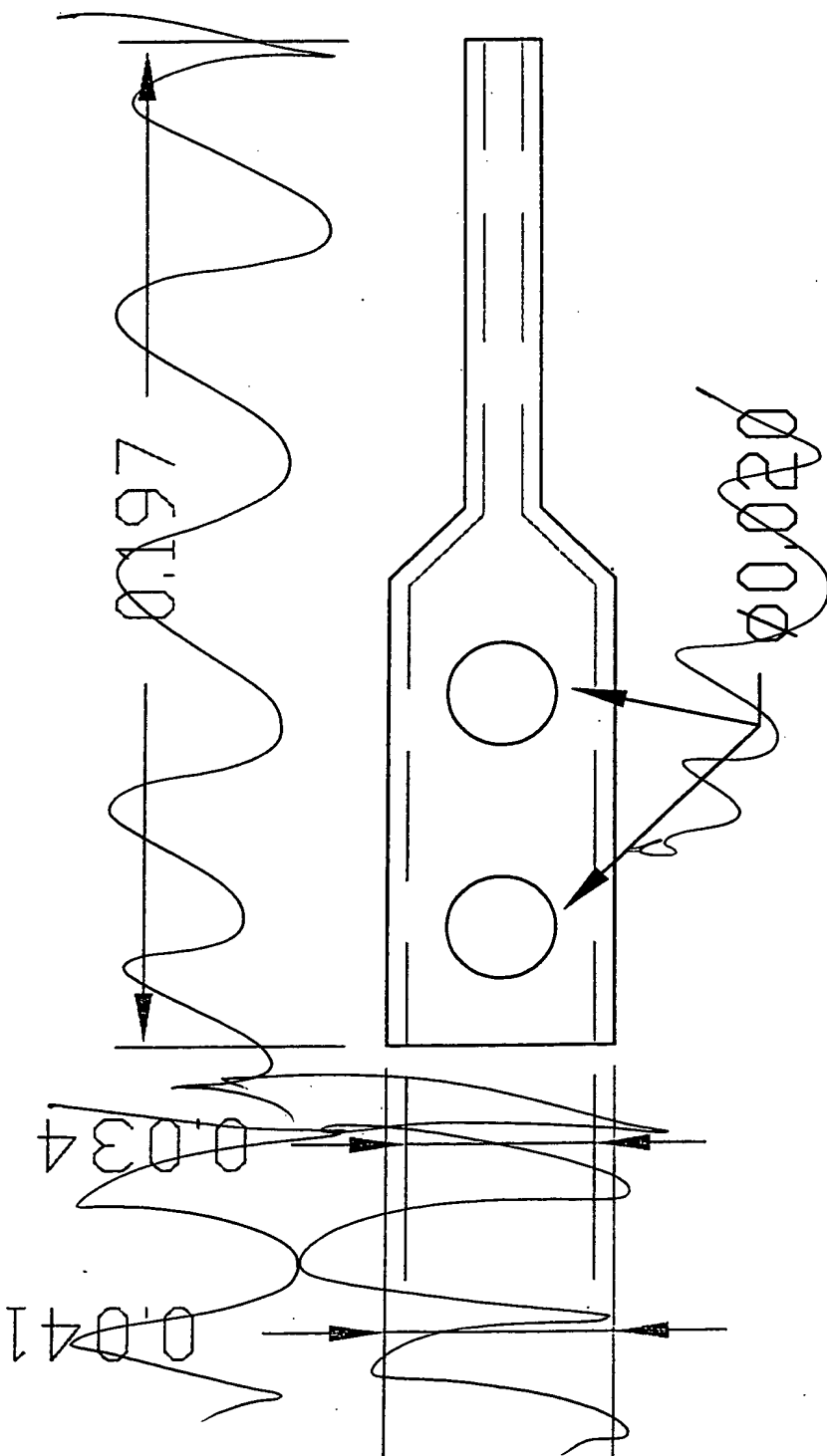


FIG. 12B

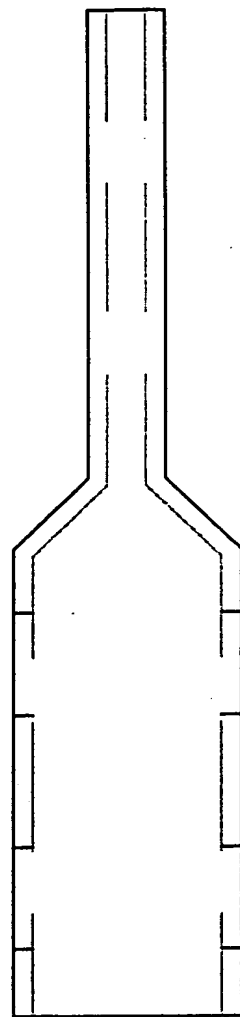


FIG. 12C

